REMARKS/ARGUMENTS

By this Amendment, claims 65-66, 68-71, 73-74, 95-100, 105, 111-112 and 121 are amended. Claims 67-69, 71-74, 95-100, 103 and 109-122 have been withdrawn from consideration pursuant to a restriction requirement. Claims 65-74 and 95-122 are pending.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

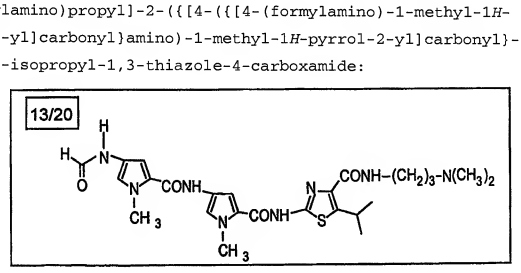
The Examiner's courtesy in granting an interview to Applicants' representative on March 19, 2009 is gratefully acknowledged. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

Amendments

The claims are amended for the reasons noted below as well as for improved consistency with U.S. practices. In addition, typographical errors are corrected in, e.g., claims 95 and 98. Support for these corrections appears in the specification at, e.g., page 18, formula II.

Restriction

Applicants gratefully acknowledge the statement in the Office Action at paragraph 3 that the elected invention, *N*-[3-(dimethylamino)propyl]-2-({[4-({[4-(formylamino)-1-methyl-1*H*-pyrrol-2-yl]carbonyl}amino)-1-methyl-1*H*-pyrrol-2-yl]carbonyl}-amino)-5-isopropyl-1,3-thiazole-4-carboxamide:



(i.e., Compound 13/20 of Fig. 3, shown above) appears to be free of the prior art.

Paragraph 3 of the Office Action goes on to state that claims 109-122 are withdrawn from further consideration as being drawn to nonelected inventions with no allowable linking claim, and claims 67-69, 71-74, 95-100 and 103 are withdrawn from further consideration as being drawn to nonelected species found in the prior art. Claim 103 is part of the elected group of claims. The other claims should be reconsidered in view of the withdrawal of the art-related rejections as agreed at the interview.

Moreover, Applicants respectfully submit that the restriction requirement failed to properly apply unity of invention practice to this national phase application. As noted in MPEP 1850:

> [T]he requirement of unity of invention referred to in [PCT] Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The compounds of base claim 65 can be depicted as follows:

R1 - (QX)a - (QY)- (QX)b - NH-A-D

wherein QX and QY represent Q as defined in Claim 65, but QY necessarily contains a branched cyclic or part-cyclic C3-5 alkyl substituent (the group R6, R7, R8, R9, R10 or R11); and a and b together represent 1 to 4. This essential structural element is absent from the compounds disclosed in the prior art.

In the light of the above, it can be seen that all of the compounds of claim 65 share as a common "special technical feature" the generic structure depicted above, which distinguishes the claimed compounds over the compounds of the prior art. Thus, under the provisions of Rule 13 PCT and MPEP 1850, it can be seen that claim 65 relates to a single invention.

This "special technical feature" of claim 65 is also shared by the withdrawn claims, which are ultimately dependent on claim 65, and therefore include the special technical feature in the claimed compounds, compositions, methods of use and processes of preparation.

Thus, pursuant to MPEP 1850, there is no basis for any finding of disunity between the various claims. The allegation by the Examiner that Rule 13 PCT does not provide for multiple compositions or multiple methods of use within a single application is unsupported by the rules. Thus, the Examiner's attempt to define different uses of the compounds of formula I as different inventions is not based in any way upon the unity provisions of the PCT, and for this reason represents an improper restriction.

Accordingly, reconsideration and withdrawal of the restriction requirement are respectfully requested.

Claim Objections

With respect to the objection to claims 101-102 and 105 as reciting non-elected inventions, there is no requirement to cancel such claims prior to allowance. Accordingly, Applicants elect not to amend these claims at the present time.

The objection to claim 70 is obviated by deleting the objectionable language from the claim. Reconsideration and withdrawal of this objection are respectfully requested.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 65-66, 70 and 103-108 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in their recitation of the expression "structural fragment(s)". This rejection is respectfully traversed.

At the interview, the Examiner agreed to withdraw this rejection if Applicants amended the claims to delete the expression. Applicants do not agree that the expression is indefinite, but have amended the claims to replace it with the term "structure". While this differs slightly from what was discussed at the interview, deleting the "structural fragment(s)" expression without replacement would have rendered certain dependent claims (e.g., claim 99) less clear.

Accordingly, reconsideration and withdrawal of the indefiniteness rejection are respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 65-66, 70 and 104-108 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

At the interview, Primary Examiner Gupta recommended that we produce evidence showing we have sufficient written description support for a representative number of species of the claimed genus. He cited as support for his position the PTO's *Written Description Examination Guidelines* (MPEP 2163). The section of the *Guidelines* relevant to the genus issue raised at the interview and in the Office Action reads as follows:

> For each claim drawn to a genus:
>
> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See [*Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998)].

However, a more complete reading of *Eli Lilly* yields the following statement of the law (which is also reproduced in the *Guidelines*, at MPEP 2163(II)(A)(3)(a)):

> **In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass**. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. **Accordingly, such a formula is normally an adequate description of the claimed genus**. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. [Emphasis added.]

The initial burden is on the PTO to show why Applicants' generic chemical formula is inadequate when such formulas are "normally an adequate description of the claimed genus."

Despite the fact that the PTO assigned this case to a biotechnology art unit, the claimed formulas define very specific chemical compounds. Thus, the written description

arguments that the Examiner might typically employ to examine DNA binding proteins of indeterminate structure, are being inappropriately applied to the claimed chemical compounds (see, e.g., page 6 of the Office Action, which states: "The MPEP further states that if a biomolecule is described only by a functional characteristic ..."). Regardless of whether the claimed chemical compounds have DNA binding properties, Applicants claim structures using structural language, not functional language as in *Eli Lilly*. The *Guidelines* and *Eli Lilly* clearly distinguish generic chemical **formulas** from **functional** definitions of biological (and other) genera. A person having ordinary skill in the art at the time of the invention would have been readily able to enumerate each and every species encompassed by the claimed genus. That the genus is large does not detract from the fact that each species is clearly defined by chemical formulas.

Moreover, the specification includes a "sufficient description of a representative number of species" of the claimed genus to further evidence possession of the claimed genus. See, e.g., MPEP 2163. In an effort to assist the Examiner with confirming this to be the case, Applicants submit herewith Annexes 1 and 2.

Annex 1 demonstrates the biological activity of 33 different species of compounds within the scope of the claimed genus, including 19 different compounds disclosed in the Examples of the application as filed. As an aid to understanding the structures of the compounds, Annex 2 provides a key to the structures of certain groups.

Each of the compounds of Annex 1 contains at least one heterocyclic "Q" group, bearing a C3-5 branched, cyclic or part-

cyclic alkyl group (e.g., isopropyl, isopentyl, cyclopropyl and cyclopentyl groups, amongst others).

The biological activities listed in Annex 1 relate to bacteria (*Staphylococcus aureus* (two strains), *Streptococcus faecalis*, *Mycobacterium fortuitum*, *Escherichia coli*, *Proteus vulgaris* and *K. aeruginosa*) and fungi (*Aspergillus niger* and *Candida albicans*). The compounds of Examples 3, 7, 12 and 33 have broad antibacterial and antifungal activity. Further, the compounds of Examples 3 (*Proteus vulgaris*) and 33 (*K. aeruginosa*), along with new compounds P21 and P22 (*Escherichia coli*) display activity against Gram negative bacteria. This appears to be a particularly unexpected advantage for these four compounds.

Accordingly, reconsideration and withdrawal of the written description rejection are respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 65-66, 70 and 104-108 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 5273991 (Moses). Claims 65-66, 70 and 104-107 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 4912199 to Lown et al.

The Examiner agreed to withdraw these rejections because they were based on a misinterpretation of the claims, as acknowledged in the Interview Summary.

Accordingly, reconsideration and withdrawal of the anticipation rejections are respectfully requested.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

April 23, 2009

By_____

David M. Tener
Registration No. 37,054
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.

ANNEX 1

Comp No.	*S.aur 1*	*S. aur 2*	*S. faec*	*A. niger*	*C. alb*	*M. fort*	*E. coli*	*Head*	1	2	3	tail
	Data are MICs as μM/ml (μg/ml); na = not active; ND = not done											
Ex 3	4.7	ND	9.5	76.1	76.1	19	200 (also *P. vulgaris* 9.5)	Fo	PyrMe	PyrMe	ThzlPr	DMAP
Ex 4	144	ND	72	72	144	72	na	Fo	Pyr*i*Pr	Pyr*i*Pr	Pyr*i*Pr	DMAP
Ex 5	6.2(9)	25(37)	25(37)	>100(>150)	50(75)	>100(>150)	na	Fo	Pyr*i*Pe	Pyr*i*Pe	Pyr*i*Pe	DMAP
Ex 6	na	ND	na	na	75	na	na	Fo	Pyr*i*Pr	PyrMe	Pyr*i*Pr	DMAP
Ex 7	4.8	ND	9.5	38.1	38.1	19	na	Fo	PyrMe	ThzlPr	PyrMe	DMAP
Ex 10	150	ND	57.5	150	150	37.5	na	Fo	PyrMe	Pyr*i*Pe	PyrMe	DMAP
Ex 11	>162(>100)	>162(>100)	>162(>100)	>162(>100)	>162(>100)	>162(>100)	na	Ac	ThzlPr	PyrMe	PyrMe	DMAP
Ex 12	4.3	ND	4.3	4.3	34.9	17.5	65	Ac	ThzlPr	Pyr*i*Me	ThzlPr	DMAP
Ex 15 (i)	na	ND	na	153	153	na	na	Ac	PyrMe	Pyr*i*Pr	PyrMe	DMAP
Ex 15 (ii)	na	ND	73.5	73.5	147	147	na	Ac	PyrMe	Pyr*i*Pe	PyrMe	DMAP
Ex 20	na	ND	74.5	74.5	na	na	na	Ac	ImiMe	PyrMe	ThzlPr	DMAP
Ex 21	na	ND	na	na	na	136	na	Ac	PyrMe	Pyr*i*Pe	PyrMe	MepipP
Ex 22	60	ND	60.4	ND	ND	ND	na	3MeOBz	PyrMe	Pyr*i*Pe	PyrMe	MepipP
Ex 24	32.7	ND	32.7	ND	ND	ND	70	3MeOBz	ThzlPr	PyrMe	PyrMe	DMAP
Ex 26	153	ND	76.9	na	76.9	38.4	na	Fo	PyrMe	PyrcPr	PyrMe	DMAP
Ex 27	75.0	ND	75	37.6	75.3	75.3	na	Fo	PyrMe	PyrcPe	PyrMe	DMAP
Ex 29	140	ND	69.3	140	na	69.3	na	Fo	PyrMe	Pyr*i*Pe	PyrMe	MepipP
Ex 32	16.2	ND	16.2	na	na	32.4	200	3MeOBz	PyrMe	Pyr*i*Pe	PyrMe	DMAP
Ex 33	15.9	ND	15.9	15.9	15.9	15.9	(15.9 *K. aeruginosa*)	4MeOBz	PyrMe	Pyr*i*Pe	PyrMe	DMAP
s03	na	ND	157	157	na	na	na	Fo	PyrMe	Pyr*i*Pr	PyrMe	DMAP
s30	70.0	ND	74.5	149	74.6	74.6	na	Ac	ThzlPr	PyrMe	PyrMe	DMAP
s48	150	ND	75.2	150	na	150	na	Fo	PyrMe	Pyr*i*Pe	PyrMe	PyrrP
p21	143(100)	143(100)	72(50)	72(50)	72(50)	143(100)	64	Ac	PyrMe	PyrMe	ThzlPe	DMAP
p22	36(25)	75(50)	36(25)	144(100)	>144(>100)	>144(>100)	50	Fo	PyrMe	PyrMe	ThzlPe	DMAP
p23	60(50)	60(50)	120(100)	>120(>100)	>120(>100)	>120(>100)	na	2,4Cl2Bz	PyrMe	PyrMe	ThzlPe	DMAP
p46	16(12.5)	32(25)	8(6.25)	>129(>100)	129(100)	>129(>100)	na	3-ClBz	PyrMe	Pyripe	PyrMe	DMAP
p47	64(50)	64(50)	127(100)	>127(>100)	>127(>100)	>127(>100)	na	3,4MDBz	PyrMe	Pyripe	PyrMe	DMAP
p48	33(25)	66(50)	33(25)	131(100)	131(100)	>131(>100)	na	3MeOBz	PyrMe	PyrMe	ThzlPr	DMAP
p49	16(12.5)	16(12.5)	8(6.25)	>130(>100)	>130(>100)	>130(>100)	na	3ClBz	PyrMe	PyrMe	ThzlPr	DMAP
p50	76(50)	153(100)	153(100)	153(100)	>153(>100)	>153(>100)	na	Ac	ThzlPr	PyrMe	PyrMe	PyrrP
p52	16(12.5)	64(50)	32(25)	>128(>100)	>128(>100)	>128(>100)	na	3,4MDBz	PyrMe	PyrMe	ThzlPr	DMAP
p54	76(50)	38(25)	38(25)	152(100)	>152(>100)	>152(>100)	na	Fo	ThzlPr	PyrMe	PyrMe	DMAP
p55	17(12.5)	17(12.5)	17(12.5)	>134(>100)	>134(>100)	>134(>100)	na	3-MeOBz	ThzlPr	PyrMe	PyrMe	Amd

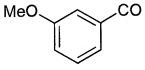
Annex 2 – Key to Compound Components

Head Groups

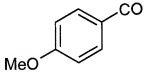
Fo HCO

Ac MeCO

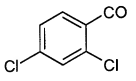
3MeOBz



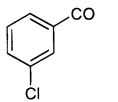
4MeOBz



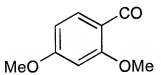
2,4Cl2Bz



3ClBz

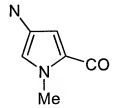


3,4MDBz

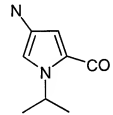


Internal Modules

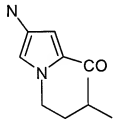
PyrMe



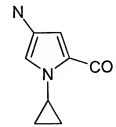
Pyr*i*Pr



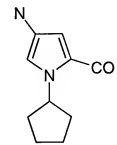
Pyr*i*Pe



PyrcPr

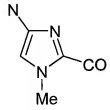


PyrcPe

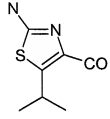


Annex 2 – Key to Compound Components

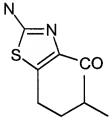
ImiMe



Thz*i*Pr

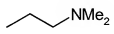


Thz*i*Pe

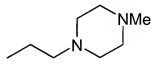


Tail Groups

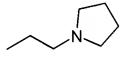
DMAP



MePipP



PyrrP



Amd